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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/785,715 | 02/16/2001 | W. Gregory Chernoff | 6631-27092 | 6811 |

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EXAMINER

FARAH, AHMED M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3739

DATE MAILED: 12/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/785,715

Applicant(s)

W. George Chernoff

Examiner

A. Farah

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 19, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 6) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant's written description fails to teach the use of fluid silicone gel as presently claimed.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, as amended, recites the limitation "a topical fluid silicone gel" applied to the scar. The term fluid silicone gel renders the claims indefinite. According to a standard English dictionary, the word 'gel' is defined as '*A colloid in which the disperse phase has*

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combined with the dispersion medium to produce a semisolid material, such as a jelly, ' and the word 'fluid' is defined as 'A continuous, amorphous substance whose molecules move freely past one another and that has the tendency to assume the shape of its container; a liquid or gas. ' Thus, it is required that the Applicant discloses/defines the degree of fluidity and/or the viscosity of the silicone gel.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

6. Claim 1 is again rejected under 35 U.S.C. 102(b) as being anticipated by Lee (U.S. Pat. No. 5,552,162).

Lee discloses a method of covering scar surface with a silicone- based gel (Col. 5, lines 5-15). Lee further describes an existing therapy for the treatment of hypertrophic scars and keloids using X-ray irradiation (Col. 4, lines 54-64).

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7. Claims 1-3 are again rejected under 35 U.S.C. 102(b) as being anticipated by Pocknell (U.S. Pat. No. 4,991,574).

Pocknell Col. 1, lines 56-59 disclose a method of applying silicone gel to a hypertrophic scar. In reference to claim 2, Pocknell teaches that the gel layer over the skin should not be so thick that it will conform substantially to the contours of the area to be treated. Therefore, to wipe off the excess gel is inherent to his invention. In reference to claim 3, he teaches a method of applying silicone-gel sheet to the hypertrophic scar (Col. 1, lines 34-56).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 4-12 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of Tankovich (U.S. Pat. No. 5,897,549).

Lee, described above, does not teach a method of treating the scar using a laser. However, Tankovich discloses an alternative method for treating hypertrophic scars using a laser (Col. 2, lines 39-46). In reference to claims 6-8 and 10-12 Table 1 and Table 2 of Tankovich clearly show a number of lasers suitable for the treatment, which can be used to obtain the parameters specified in the instant claims such as the pulse duration, beam spot size, and the energy density.

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In reference to claim 5, these lasers include a dye laser with wavelength range of 550 nm to 650 nm. Therefore, it would have been obvious to one having ordinary skill in the art, at the time of the applicant's invention, to modify the method described in Lee's invention, and employ lasers as described by Tankovich instead of the X-ray irradiation in order to treat the scars and avoid the potential skin cancer of the X-ray therapy.

Response to Arguments

10. Applicant's arguments filed August 19, 2002 have been fully considered but they are not persuasive. The applicant's amended claims 1-3 recite the limitation "fluid silicone gel." Hence, based on this ~~am~~endment, the applicant argues that the prior art of record fails to teach the features of the instant claims, i.e., fluid silicone gel.

In response to this arguments, Lee ('162) teaches that "silicones are oils of very low melting point, while ^{at} the other end of the scale of physical properties are highly cross-linked silicones which form rigid s^olid." He further teaches that silicone gels release a low molecular weight silicone fluids. See Col. 5, lines 19-22 and 31-34. Therefore, the Examiner's position is that Lee's silicone gel meets the claimed limitation.

Furthermore, the applicant implies that the fluid silicone gel has different physical properties from a silicone gel. In response to this argument, it is required that the applicant clearly describe such differences both in the written description and the claim language.

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Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 5,741,509 to Kushner teaches a wound dressing comprising a blend of silicone fluid and fumed silica. See the abstract and claims 1 and 7.

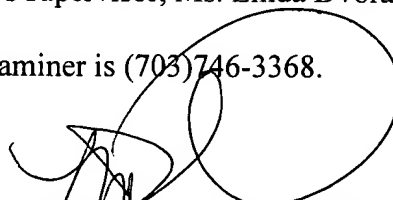
12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. Farah whose telephone number is (703) 305-5787. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Linda Dvorak, can be reached on (703) 308-0994. The fax number for the Examiner is (703) 746-3368.

A. M. Farah (Examiner)

AMF
11/22/02


Linda C. M. Dvorak (SPE)

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